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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL

MAY 1, 1986

NOTICE

This will be the last Reagents Evaluation Report issued by the Reagents Evaluation Branch, Biological Products Program, Center for Infectious Diseases (CID). The Evaluation Program has been abolished, and there are no plans to continue a formal evaluation program for commercial reagents except for certain reagents for tests for syphilis. The latter will continue to be evaluated by the Sexually Transmitted Diseases Laboratory Program, CID.

Reference Reagents will continue to be distributed in the same manner as in the past.

We regret having to discontinue this evaluation program and hope it has been of value to you.

W. Knox Harrell, Ph.D.
Director,
Biological Products Program

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May 1, 1986

REAGENTS EVALUATION REPORT

March 1 - April 30, 1986

Identification of commercial reagents submitted to this laboratory for evaluation and which met CDC performance specifications is provided for your information. During this period, 102 lots of microbiological reagents were evaluated and 89% met CDC specifications.

Samples of lots of commercial reagents are tested by methods described in CDC specifications. Inclusion in the monthly report verifies the acceptable performance of samples of the reagent in the stated test system. It does not, however, verify the usefulness of the test system either in general or as specified by the producer. Our testing does not replace the quality control procedures consumers should perform.

To order products tested and found to be satisfactory by CDC, consumers should specify the product by name, not by lot number, and indicate that it must have been evaluated by CDC; then use the monthly reports to verify lot numbers.

For information about the products listed or about the reagents evaluation program, write or phone:

Director,
Biological Products Program, CID, CDC
Atlanta, Georgia 30333
(404) 329-3352

REAGENTS TESTED AND FOUND TO MEET CDC SPECIFICATIONS

Bacterial - Syphilis Serology

Source	Identification	Package Size
FLUORESCEIN-LABELED ANTI-HUMAN GLOBULIN (For use in the FTA-ABS test)		
Clinical Sciences	1026P001	0.5 ml
Difco	743769	5.0 ml
FLUORESCENT TREPONEMAL ANTIBODY (FTA) TEST ANTIGEN (For use in the FTA-ABS test)		
BBL	B8GFHC	1.0 ml
	B8GFHI	1.0 ml
Clinical Sciences	1014P002	10-test pre-
	1014P003	pared slide
	1023P003	
	1023P004	
	1023P005	
	1023P007	
	1408P003	1.0 ml bottle
FLUORESCENT TREPONEMAL ANTIBODY-ABSORPTION (FTA-ABS) TEST SORBENT (For use in the FTA-ABS test)		
BBL	B8GFHS	5.0 ml bottle
	B8GFIF	5.0 ml bottle
Clinical Sciences	1041P001	10.0 ml bottl
FTA-ABS TEST REACTIVE CONTROL SERUM		
Clinical Sciences	1031P001	1.0 ml bottle
	1031P002	1.0 ml bottle
	1031P003	1.0 ml bottle
FTA-ABS TEST NONSPECIFIC CONTROL SERUM		
Clinical Sciences	1032P001	1.0 ml bottle

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USR ANTIGEN SUSPENSION
(For use in the USR test)

Difco	742904	3.0 ml bottle
Gamma	246-57	3.0 ml bottle

VDRL ANTIGEN

Roach	1013-116	Bulk

CONTROL SERUM

Source	Identification	Package Size	Test Reactivity Pattern
BBL	B8GFGX B8GFGY	3.0 ml bottle (dehydrated)	Reactive in VDRL serum, VDRL spinal fluid, and USR tests
GIBCO	90N1161	5.0 ml bottle	Reactive in VDRL test
	90N2260 91N2260	5.0 ml bottle	Weakly reactive in VDRL test
	92K6062	5.0 ml bottle	Negative in VDRL test

CONTROL SERUM (SETS)

Source	Identification	Package Size	Test Reactivity Pattern
Difco	740227 742141	3.0 ml bottle each (dehyd.)	Reactive, Weakly Reactive, and Nonreactive in the VDRL test.
	742729	3.0 ml bottle each (dehyd.)	Reactive, Weakly Reactive, and Nonreactive in the USR test.
Hynson, Westcott & Dunning	631 632 633	10 cards	Reactive, Reactive, minimal to moderate and Nonreactive in RPR(18 mm circle) card test

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MULTIPLE COMPONENT SYSTEMS

Source	Product		Identification
Ames	Microhemagglutination Assay for Treponema pallidum Antibodies (MHA-TP)	Kit No. 2900	0220026
		Kit No. 2910	0130016
		Kit No. 2910	0227026
Clinical Sciences	FTA-ABS Test Kit		1910P007 1912P001
Difco	Hemagglutination Treponemal Test for Syphilis (HATTS)		740826
Fisher	Reagin Screen Test		632-125

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REAGENTS TESTED AND FOUND TO MEET CDC SPECIFICATIONS

BACTERIAL - GENERAL

Product	Test System	Company	Control/ Lot No.	Package Size
Refer to pages 9 and 10 for Streptococcus grouping reagents.				
Antisera				
Salmonella Group C_2	Latex Aggl.	Fisher Diag.	178-115	1.0 ml

MYCOPLASMAL

Antigens				
Mycoplasma pneumoniae	CF	M.A. Bioproducts	42121	5.0 ml
			42141	5.0 ml

MYCOTIC

Cryptococcosis	Latex Aggl.	Meridian Diagnostics	K404A21	1 kit
			K404A22	1 kit
			K404A23	1 kit
			K404A24	1 kit
			K404A25	1 kit
			K404A26	1 kit

PARASITIC

Antigens				
Toxoplasma gondii	IFA	Microbiological Research Corp.	T01S/6	10-well slide
			T02S/6	10-well slide
			T03S/6	10-well slide
			T04S/6	10-well slide
Multiple Component Systems				
Toxo Test	IFA	Microbiological Research Corp.	GK05T/6	1 kit

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VIRAL

Product	Test System	Company	Control/ Lot No.	Package Size
Antigens				
Herpesvirus	CF	M.A. Bioproducts	41933 42055	5.0 ml 1.0 ml
Influenza, Type A	CF	M.A. Bioproducts	42106	5.0 ml
Influenza, Type B	CF	M.A. Bioproducts	42109	5.0 ml
Measlesvirus	CF	M.A. Bioproducts	42031	1.0 ml
Mumpsvirus	CF	M.A. Bioproducts	42138	5.0 ml
Parainfluenza, Type 2	CF	M.A. Bioproducts	42003 42129	5.0 ml 5.0 ml
Parainfluenza, Type 3	CF	M.A. Bioproducts	42127 42144	5.0 ml 5.0 ml
Multiple Component Systems - Rubella				
Erythrocyte Suspension	HAI	Behring Diagnostics	65B092 65B153	6.0 ml 6.0 ml
Control Serum Set	HAI	GIBCO/Sylvana	90N0160	1 set
Rubella (IgM)	EIA	Abbott	85-587S0	1 kit
Rubella	EIA	Behring Diagnostics	660178	1 kit
Rubella	EIA	M.A. Bioproducts	12973 13135 13248 13255 13341 13358 13360 13446	1 kit 1 kit 1 kit 1 kit 1 kit 1 kit 1 kit 1 kit
Rubella	PHA	Abbott	86-592S0	1 kit
Rubella	Latex Aggl. (Quan.)	Hynson, Westcott & Dunning	226 227 228 229	1 kit 1 kit 1 kit 1 kit

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ANNOUNCEMENT

Change in Rubella Antibody Kit Evaluation Program

As announced in the May 1, 1984 monthly report, the Evaluation Branch has discontinued the 100% lot-to-lot testing of those rubella antibody kits which have proved to be of high quality in our rubella evaluation program over a period of time. Please refer to the May 1 monthly report for more details of this change in our program. The rubella antibody kits which have been in special status of reduced testing are listed below.

Rubella Antibody Kits in Special Status of Reduced Testing

Type	Company	Name of Kit
HAI Heparin-$MnCl_2$	Behring Diagnostics	Rubesure
HAI Heparin-$MnCl_2$	Ortho	Rubindex
Passive Hemagglutination	Abbott	Rubacell
Passive Hemagglutination	Behring Diagnostics	PHAST
Enzyme Immunoassay	Abbott	Rubazyme
Latex Agglutination (Qualitative)	Hynson, Westcott & Dunning	Rubascan
Fluoroimmunoassay	International Diagnostic Technology (M.A. Bioproducts)	FIAX Rubella G

REAGENTS EVALUATION PROGRAM
Current Product List of Streptococcus Grouping Reagents*

May 1, 1986

Antisera for Capillary-Precipitin Test

Manufacturer	Group	Lot No.	Expiration Date	Date Tested
BBL	A	I5HDLT	Jun 86	Jan 84
Lee	A	F04311	Jun 87	Oct 84
Lee	B	F03409	Jun 86	Oct 83
Lee	C	F04381	Oct 87	Apr 85
Lee	D	F03796	Nov 86	Jan 84
Lee	F	F03797	Mar 87	Jul 84
Roach	A	4000-01	Jan 88	May 85
Roach	B	4001-01	Jan 88	May 85
Roach	C	4002-01	Jan 88	May 85
Roach	D	4003-01	Jan 88	May 85
Roach	E	4004-01	Jan 88	May 85
Roach	F	4005-01	Jan 88	May 85
Roach	G	4006-01	Jan 88	May 85
Wellcome	A	K309410	Jul 87	Oct 85
Wellcome	A	K102410	Jan 87	Jul 85
Wellcome	A	K102510	Jan 87	Jul 85
Wellcome	A	K963710	May 86	Apr 85
Wellcome	A	K055810	Sep 86	Jan 85
Wellcome	B	K450410	Jan 88	Apr 86
Wellcome	B	K383810	Oct 87	Jan 86
Wellcome	B	K299510	Jul 87	Oct 85
Wellcome	B	K211510	Mar 87	Jul 85
Wellcome	B	K211520	Mar 87	Jul 85
Wellcome	B	K881310	May 86	Oct 84
Wellcome	B	K963810	May 86	Jul 84
Wellcome	C	K383910	Oct 87	Jan 86
Wellcome	C	K207610	Mar 87	Jul 85
Wellcome	C	K061810	Oct 86	Apr 85
Wellcome	D	K359910	Aug 87	Jan 86
Wellcome	D	K207710	Mar 87	Jul 85
Wellcome	D	K055910	Sep 86	Jan 85
Wellcome	E	K397020	Oct 87	Apr 86
Wellcome	E	K397010	Oct 87	Apr 86
Wellcome	E	K314410	Jul 87	Oct 85
Wellcome	E	K097710	Nov 86	Apr 85
Wellcome	E	K056010	Oct 86	Jan 85
Wellcome	F	K056110	Oct 86	Jan 85
Wellcome	F	K884510	May 86	Jul 84
Wellcome	G	K315110	Jul 87	Oct 85
Wellcome	G	K207810	Mar 87	Jul 85
Wellcome	G	K056210	Sep 86	Apr 85

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Manufacturer	Test	Groups	Lot No.	Expiration Date	Date Tested
BBL	BBL Strep Grouping Kit Latex Agglutination	A,B,C,F,G	I6HEDG	Jun 87	Jan 86
			F6HEDE	Mar 87	Jan 86
			F6HEDF	Mar 87	Jan 86
			F6HEBC	Mar 87	Oct 85
			E6HEAO	Feb 87	Oct 85
			C6HDZB	Dec 86	Jul 85
			J5HDVA	Jul 86	Jan 85
			J5HDUY	Jul 86	Jan 85
Meridian	MERITEC-Coagglutination	A,B,C,F,G	KC06015	Jun 87	Apr 86
			KC06012	Feb 87	Oct 85
			KC06010	Nov 86	Jul 85
			KC06005	Jun 86	Apr 85
			KC06004	May 86	Jan 85
Oxoid Ltd.	Streptococcal Grouping Kit Latex Agglutination	A,B,C,D,F,G	67251	Jan 87	Apr 86
Pharmacia	Phadebact Coagglutination	A,B,C,G	1584	Nov 86	Jan 86
			1583	Jul 86	Jan 86
			1563	Jul 86	Oct 85
			1032	May 86	Jul 85
Wellcome	Streptex, Latex Agglutination	A,B,C,D,F,G	K360110	Aug 86	Jan 86
			K360111	Aug 86	Jan 86
			K336211	Jul 86	Jan 86
			K323411	Jul 86	Jan 86
			K323410	Jul 86	Jan 86
			K336210	Jul 86	Jan 86
			K296810	Jul 86	Oct 85
			K258010	May 86	Jul 85
			K487210	Jan 87	Apr 86
			K487110	Jan 87	Apr 86
			K460010	Dec 86	Apr 86
			K440710	Dec 86	Apr 86

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